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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,997	09/12/2003	David J. Ecker	IBIS0063-100/DIBIS-0002US	7707

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/660,997	<b>Applicant(s)</b> ECKER ET AL.	
	<b>Examiner</b> Jeffrey Fredman	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14,15,29-32 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14,15,29-32 and 34-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status**

1. Claims 14,15,29-32 and 34-38 are pending.

Claims 14,15,29-32 and 34-38 are rejected.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14,15,29-32 and 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes " If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

Here, claim 14 incorporates a range of 8 in the comparison of calculated bioagents and this number and new range is apparently new matter. A careful review by the examiner of the cited pages of the specification failed to identify any support for this new limitation. The citation to Figure 14 does not support a comparison to 8, since

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the listed eight elements are not comparable and the figure shows much more than 8 elements. The eight elements listed include species such as hepatitis A virus and includes genera such as Rhinovirus, which includes dozens if not hundreds of members. So Rhinovirus is not a single "bioagent" as per claim 1. As noted by MPEP 2163.05,

"With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure."

In this case, no basis for the range of 8 or more bioagents has been identified in the original disclosure. The disclosure at figure 14 shows at least 25-30 different different results, not 8. This conclusion is consistent with the decision of the Federal Circuit in Eiselstein v. Frank 34 USPQ2d 1467, 1471 (Fed. Cir. 1995), where the Court noted "Moreover, the 10% range of 45-55%, even if it is an approximate "about" 45-55%, is not the same as a very different 10% range, viz. , 50-60%. The limits of these ranges vary from each other by about 10%, which is comparable to the extent of the variation within each range. Eiselstein has therefore not persuaded us that the Board clearly erred in finding that the grandparent application did not provide an adequate written description of the invention comprising 50-60% nickel." Thus, the Federal Circuit did not permit a range shift where the prior range was disclosed in a way inherently shown in the specification. The change in the current case is greater since there is no support for the specific range chosen whatsoever. Since no basis has been found to support the new claim limitation in the specification, the claim is rejected as incorporating new matter.

***Claim Rejections - 35 USC § 112***

4. The rejection of claims 14-19 and 29-38 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment.

***Claim Rejections - 35 USC § 102***

5. The rejection of claims 14, 15, 29 and 30 under 35 U.S.C. 102(b) as being anticipated by Muddiman et al (1997) 69:1543-1549) as evidenced by Muddiman et al (Anal. Chem. (1996) 68:3705-3712) is withdrawn in view of the amendment and declaration.

***Claim Rejections - 35 USC § 103***

6. The rejection of claims 17, 18, 31, 32, 34, 35, 37 and 38 under 35 U.S.C. 103(a) as being unpatentable over Muddiman et al (1997) 69:1543-1549) as evidenced by Muddiman et al (Anal. Chem. (1996) 68:3705-3712) in view of Nakao et al (J. Clin. Microbiol. (1997) 35(7):1651-1655) is withdrawn in view of the amendment and declaration.

7. The rejection of claims 16 and 33 is moot in view of the cancellation of those claims.

8. The rejection of claims 17-19, 31, 32, and 34-38 under 35 U.S.C. 103(a) as being unpatentable over Muddiman et al (1997) 69:1543-1549) as evidenced by Muddiman et al (Anal. Chem. (1996) 68:3705-3712) in view of Nishikawa (FEMS Microbiol. Letters (1999) 178:13-18) is withdrawn in view of the amendment and declaration.

***Double Patenting***

9. The double patenting rejections are withdrawn in view of the terminal disclaimers filed over the related applications.

***Response to Declaration***

10. The Declaration under 37 CFR 1.132 filed August 31, 2006 is sufficient to overcome the rejection of claims 14,15,29-32 and 34-38 based upon 35 U.S.C. 103 since the declaration demonstrated skepticism in the art of experts, specifically the JASONS, which secondary consideration overcomes the obviousness rejections.

***Response to Arguments***

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

9/13/06